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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/750,545	KAISER, JON D.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/12/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the receipt of Applicant's response to the restriction requirement filed on 1/12/2006. Applicant elected with traverse the invention of Group I claims 1-27. Applicant agreed that the claims of Group I are patentably distinct from the claims of Groups II-XI and traversed on the grounds that the method claims employ the nutrient composition of the Group I claims and it would not represent a burden of search on the Examiner because the searches substantially overlap. The Examiner respectfully disagrees with this view as the methods are drawn to different patient populations with different pathologies. The Examiner maintains that a search, for example, for a method of augmenting a therapeutic treatment of radiation poisoning would not overlap with a method of augmenting a therapeutic treatment of heart disease and thus become a burden of search on the Examiner and the restriction is made final. Withdrawn method claims that depend from or otherwise include all the limitations of patentable product/composition claims, i.e., commensurate in scope with an allowed product/composition claims, will be rejoined.

Accordingly, claims 1-27 are presented for examination on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorsek (US 6,103,756).

Instant claim 1 is drawn to a nutrient composition for augmenting immune strength or physiological detoxification comprising an optimal combination of a substantially pure and an effective amount of at least one vitamin antioxidant, at least one mineral antioxidant and a highly saturable amount of at least three high potency antioxidants.

By substantially pure, Applicants means:

> [088] The nutrients of the invention and optimal combinations in the compositions of the invention can have a purity level greater than about 90%, preferably greater than about 95% and more preferably greater than about 98%. Purity levels greater than about 98% percent can also have a purity of about 99% or greater as determined, for example, by total weight of the nutrient composition. These higher purity levels can be obtained by, for example, methods well known in the art. Additionally, purity levels greater than about 98% and particularly greater than about 99% by total weight can be obtained by omitting fillers, binders or lubricants such as stearates or palmitates. Additionally, other substances which are known in the art to inhibit, or known to possibly inhibit, the absorption, bioavailability or tolerance of compounds in individuals also can be excluded from the formulations to achieve greater than about 98-99% purity without compromising the activity of the nutrient compositions of the invention. However, it should be

(Instant specification, page 27, [088]).

By highly saturable, Applicant means:

> [027] As used herein, the term "highly saturable amount" when used in reference to a high potency antioxidant is intended to mean an amount of high potency antioxidant that maintains an excess of reduction potential during the course of treatment. Highly saturable amounts are in excess of the RDA, preferably in about 10-fold excess of the RDA and more preferably in about 20-fold excess of the RDA. Specific examples of highly saturable amounts for the high potency

(Instant specification, page 9, [027]).

Gorsek discloses a formulation comprising: 100-6000 mg vitamin C; 100-2000 IU of vitamin E; 100-20000 IU vitamin A; 50-600 mcg selenium; and 4 high potency antioxidants: 50-1000 mg alpha lipoic acid; 10-1000 mg quercetin; 10-1000 mg rutin; and 10-1000 mg of citrus bioflavonoids (Column 1, lines 56-65 and claim 3). Since there are no fillers, binders or lubricants, then the Examiner interprets this composition to be substantially pure and read upon instant claims 1, 4-6 and 8-11.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, (for augmenting immune strength or physiological detoxification) however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Claim Rejections - 35 USC § 103

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosbab (US 2001/0031744).

Kosbab teaches therapeutic compositions and provides an exemplary formulation dosage comprising at least one vitamin antioxidant, at least one mineral antioxidant and at least three high potency antioxidants: 1000 mg vitamin C; 714 mg vitamin E; 4.88 mg vitamin B6; 5000 IU vitamin A; 30 mg zinc; 20 mg alpha lipoic acid; 200 mg N-acetyl-cysteine; 50 mg acetyl L-carnitine (Page 21, Table 4). Kosbab teaches preferred dosage ranges for exemplary formula components: 10-5000 mg vitamin C; 5-800 mg vitamin E; 0.001-200 mg vitamin B6; 1000-25000 IU vitamin A; 1-2000 mg quercitin (bioflavonoids); 10-3000 mg zinc; 0.001-50 mg selenium; 5-1000 mg alpha lipoic acid; 5-3000 mg N-acetyl-cysteine; and 10-3000 mg acetyl L-carnitine (Page 21, Table 3). Kosbab does not add fillers, binders or lubricants so the composition is substantially pure. The weight range of high potency antioxidants that can be in the composition of Kosbab encompasses the amount as disclosed in the instant specification in Figure 1:

Three colored capsules contain:

Alpha Lipoic Acid	200 mg
Acetyl L-Carnitine	500 mg
N-Acetyl Cysteine	600 mg

Figure 1

1. Kosbab does not expressly disclose a nutrient composition comprising highly saturable amounts of at least three high potency antioxidants.

2. Kosbab does not expressly disclose a nutrient composition with at least three vitamin antioxidants, at least two mineral antioxidants and at least 3 high potency antioxidants.

3. Kosbab does not expressly disclose a nutrient composition for augmenting immune strength or physiological detoxification comprising an optimal combination of a substantially pure and an effective amount of vitamin C, bioflavonoid complex, vitamin E, zinc, selenium, alpha lipoic acid, acetyl L-carnitine and N-acetyl-cysteine.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Kosbab to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Kosbab provides the preferred dosage ranges of formula components such that one of ordinary skill in the art could reduce to practice the instant invention by: 1) adding highly saturable amounts of at least 3 high potency antioxidants; 2) adding selenium as

another mineral antioxidant and produce a formula comprising 3) vitamin C, bioflavonoid complex, vitamin E, zinc, selenium, alpha lipoic acid, acetyl L-carnitine and N-acetyl-cysteine.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, (for augmenting immune strength or physiological detoxification) however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek (US 6,103,756) in view of Ames et al. (US 5,916,912) and Kosbab (US 2001/0031744).

The references of Gorsek and Kosbab are discussed above and that discussion is hereby incorporated by reference.

1. Gorsek does not expressly disclose a nutrient composition comprising acetyl L-carnitine. Gorsek teaches a serving size contained in 6 capsules that comprising: 150 mg alpha lipoic acid; 200 mg N-acetyl-cysteine; 10 mg glutathione; 1.5 g vitamin C; 500 IU vitamin E; 17,500 IU vitamin A; 800 mcg folic acid; 50 mg vitamin B6; 25 mg zinc; 200 mcg selenium and 450 mg of bioflavonoids from 3 sources. Gorsek teaches a nutrient composition with at least three vitamin antioxidants, at least two mineral antioxidants and at least 3 high potency antioxidants. Gorsek teaches that one skilled in the art can easily modify or change the formulation within the specific description to provide a unique product (Column 2, lines 25-27). The Examiner interprets this to mean that one of ordinary skill in the art can add or subtract to the amount of each ingredient.

2. Gorsek does not expressly disclose a nutrient composition for augmenting immune strength or physiological detoxification comprising an optimal combination of a substantially pure and an effective amount of vitamin C, bioflavonoid complex, vitamin E, zinc, selenium, alpha lipoic acid, acetyl L-carnitine and N-acetyl-cysteine. The reference of Gorsek is lacking acetyl L-carnitine.

Ames et al. teaches a formulation comprising at least one antioxidant (250 mg of: glutathione, N-acetyl cysteine and lipoic acid) and 250 mg of acetyl L-carnitine (Claims 1, 6, 8 and 10, for example). Ames et al. disclose the beneficial effect of administering the combination on restoring mitochondrial function in older animals (Column 1, lines 40-47).

Kosbab teaches the amount of antioxidants to use in the composition (Page 21, Table 3).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Gorsek with a highly saturable amount of acetyl L-carnitine, as suggested by Ames et al. and Kosbab, for the purpose of reversing the indicia of aging, as taught by Ames et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because restoration of youth is a desirable health benefit as well as an excellent marketing feature to the composition.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, (for augmenting immune strength or physiological detoxification) however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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